

REMARKS

The present invention relates to devices that provide for measurement of at least one analyte of interest through the use of biosensors, and methods for their use. These devices comprise, *inter alia*, at least two device regions: a first region for receiving a fluid sample, and a second region in fluid communication with the first region and comprising one or more capture zones. The capture zone(s) comprise molecules of a first receptor reactive with an analyte of interest, and at least one analyte sensor that detects an electrochemical signal related to reaction of a detectable amount of said analyte of interest with the first receptor.

The present application claims priority to a number of predecessor applications, many of which have issued as U.S. patents. One such application, U.S. patent application Ser. No. 08/902,775, issued as U.S. Pat. No. 6,271,040, has claims related to those instantly filed in that the former are directed to assay devices that measure analyte through the use of biosensors. This information is provided solely for the convenience of the Examiner, and is not to be considered an admission that the instantly filed claims are variants of the claims issued in the '040 patent.

The earliest application to which the present application claims priority is U.S. patent application Ser. No. 07/887,526, issued as U.S. Pat. No. 5,458,852, which was filed on May 21, 1992. For the convenience of the Examiner, the following chart provides a listing of where exemplary support for each element of the present claims may be found in the '852 patent. This listing is not meant to be limiting, and additional support for various elements of the claims may be found throughout the various priority documents.

1. An assay device comprising:

a housing;

Col. 5, lines 3-6

a first device region formed by or within said housing for receiving a fluid sample; and

Col. 5, lines 47-52

a second device region fluidly connected to said first device region, said second device region comprising one or more capture zones on a surface within said housing, each said capture zone comprising molecules of a first receptor reactive with an analyte of interest and at least one analyte sensor configured and arranged to detect an electrochemical signal related to reaction of a detectable amount of said analyte with molecules of said first receptor and produce a measurable signal in response;

Col. 10, lines 24-27; col. Col 10, lines 10-16

wherein said assay device is configured and arranged to deliver a predetermined volume of said fluid sample from said first device region to said second device region for determining the presence or amount of one or more analytes of interest therein.

Col. 6, lines 7-17

2. An assay device according to claim 1, wherein the molecules of said first receptor is an antibody or a binding fragment thereof.

Col. 3, lines 7-9

3. An assay device according to claim 1, further comprising one or more reagents disposed in the device for mixing with said predetermined volume of said fluid sample to form a reaction mixture when said predetermined volume is delivered from said first device region to said second device region.

Col. 6, line 64 – col. 7, line 2.

4. An assay device according to claim 3, wherein said one or more reagents comprise one or more labeled reagent species, wherein molecules of each said labeled reagent species comprise an enzyme conjugated to a second receptor reactive with said analyte of interest, wherein molecules of said labeled reagent species form sandwich complexes with molecules of said analyte of interest and with molecules of said first receptor.

5. An assay device according to claim 1, wherein said first receptor is bound to one or more latex particles, and said latex particles are bound to said capture zone.

6. An assay device according to claim 1, comprising a plurality of capture zones corresponding to a plurality of different analytes of interest.

7. An assay device according to claim 1, wherein said predetermined volume of said fluid sample is delivered from said first device region to said second device region by capillary action.

8. An assay device according to claim 1, wherein said analyte sensor uses amperometric measurements to detect said electrochemical signal.

9. An assay device according to claim 1, wherein said analyte sensor uses potentiometric measurements to detect said electrochemical signal.

10. An assay device according to claim 1, wherein said surface within said housing comprising capture zones is an inner surface of the housing.

Col. 3, lines 15-30

Col. 14, lines 25-55

Col. 10, lines 39-43

Col. 10, lines 19-21

Col. 5, lines 3-6

Col. 3, line 59

Col. 3, line 58

Example 4, cols. 19-20.

Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

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